In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-216V
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To be Published

JEFFREY DAVID SIMMONS,	*	
	*	
Petitioner,	*	
	*	
v.	*	Tdap vaccine; anaphylactoid response;
	*	immune problems; Addison's-like disease
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Justine E. Walters, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

On April 7, 2011, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that the Tdap ("tetanus toxoid-diphtheria-acellular pertussis") vaccine he received on April 11, 2008 caused him anaphylaxis, immune dysregulation, and autoimmune disease leading to Addison's disease.[2] Pet., at ¶ 107.

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access. On November 5, 2015, petitioner moved to redact the ruling on entitlement. The undersigned grants petitioner's motion.

[2] Addison's disease is "a chronic type of adrenocortical insufficiency, characterized by hypotension, weight loss, anorexia, weakness, and a bronzelike hyperpigmentation of the skin. It is due to tuberculosis- or autoimmune-induced destruction of the adrenal cortex, which results in deficiency of aldosterone and cortisol and is fatal in the absence of replacement therapy." Dorland's Illustrated Medical Dictionary 528 (32d ed. 2012) (hereinafter, "Dorland's").

The undersigned held a hearing on July 9 and 10, 2015, during which respondent's expert, Dr. Arnold I. Levinson, an immunologist, agreed with petitioner's expert, Dr. Joseph A. Bellanti, also an immunologist, that petitioner had a vaccine reaction. However, Dr. Levinson did not know how long petitioner's reaction lasted. He opined that petitioner's Addison's disease was not related to his vaccine reaction.

Thus, this decision starts with the undisputed opinion that petitioner had a vaccine reaction, discusses further whether it lasted beyond the statutorily-required six months, and whether petitioner's Addison's or Addison's-like disease is a sequelae of his vaccine reaction. The undersigned holds that petitioner still has residua of his vaccine reaction, satisfying the statutory requirement of more than six months of sequelae, and that his Addison's disease is part of that sequelae.

FACTS

Pre-vaccination records

Petitioner was born on August 5, 1969. According to his mother's affidavit, he could not digest milk as a baby. Ex. 42, at 1. Petitioner received his first DPT at two months of age, following which he would be fussy for days, develop body rashes and hives, have swelling at the injection site, high fevers, and enlarged lymph nodes. Id. at 2. When he was seven months old, petitioner had trouble breathing and developed daily asthma attacks. Id. Petitioner avoided drinking milk as a child because he experienced cramping and nausea. Id.

On November 2, 2006, Dr. Kenneth D. Fine of EnteroLab wrote a report stating that a stool sample from petitioner showed that petitioner had sensitivity to gluten and casein (cow's milk) in the form of IgA antibody. Med. recs. Ex. 2, at 75 (also at 105 and Ex. 6, at 4).

Post-vaccination records

On Friday, April 11, 2008, petitioner saw his personal care physician Dr. Ross Bethel for a medical examination. Med. recs. Ex. 3, at 11. Petitioner had a history of headaches, asthma, gluten sensitivity, and increased blood pressure, but not hypertension. Id. Petitioner received the Tdap vaccine at this examination. Id.

Three days later, on Monday, April 14, 2008, petitioner returned to Dr. Bethel, complaining of mild redness of his left deltoid without tenderness. Id. at 9. Petitioner also had left axillary (armpit) adenopathy with tenderness, and mild swelling in the left axilla on the chest side. Id. Dr. Bethel noted that petitioner had a reaction to his recent pertussis vaccination: "He is having a vigorous immune response to the pertussis component of the Tdap." Id. Dr. Bethel continues in his record that, on Friday, petitioner received Tdap in his left deltoid. Id. at 8. Over the weekend, he developed headache, fevers, left axillary pain and swelling, muscle pain in his deltoid and left pectoral area, and low-grade chills. Id. His noted that his left arm felt funny. Id.

On June 17, 2008, petitioner saw Dr. Rick D. Gross for a nasopharyngoscopy, which showed petitioner had reflux and thrush. Med. recs. Ex. 5, at 12.

On September 18, 2008, petitioner returned to Dr. Bethel. Med. recs. Ex. 3, at 6. The medical records for this visit note that, about five months previously, petitioner received Tdap. Id. Dr. Bethel writes, "He reacted very poorly to this and we suspect it might be because it contains some casein. He has known sensitivity to casein and gluten. He developed quite a wide variety of symptoms. One of them is flank[ ] pain and that has never gone away." Id. Petitioner also developed sharp left-sided neck pain. Id. at 7. Nasopharyngoscopy showed he had a "rip roaring case of Candida." Id. Petitioner still had left-sided neck pain. Id. Dr. Bethel writes that he is "wondering whether his immune reaction to the Tdap is somehow contribut[ing] to these other symptoms he continues having. Concerned about his kidneys because of the flank pain." Id. Petitioner had urinary frequency and some urgency going on for some time. Id.

On November 4, 2008, petitioner saw Dr. Richard Wilkinson, a specialist in allergy and asthma. Med. recs. Ex. 2, at 104. Petitioner told Dr. Wilkinson that he had issues with gluten and casein sensitivity for much of his life. Id. He received a tetanus vaccination on April 11, 2008. Id. For the next 24 hours, he had symptoms of anaphylaxis without throat closing. Id. The vaccine had casein in it. Id. Since then, petitioner stated, he had been trying to get better. Id. He received the vaccination in the left deltoid and the arm was very sore without numbness. Id. at 103. The day after the vaccination, his axillary lymph node was the size of a grapefruit. Id. He had fever and chills and felt as if he were going to pass out. Id. He got a bad headache, hives, and then blisters which itched and were painful. Id. He had hair loss, significant chest pain, dizziness, vertigo, severe, sharp pain in his throat, fatigue, joint pain, acid reflux, diarrhea alternating with constipation, puffy eyes, thrush, significant flank pain, pain in the kidney areas, nocturnal sweats, and sensitivity to cold and heat. Id. at 102-03.

On June 16, 2009, Dr. Wilkinson wrote a letter. It is unclear to whom he wrote it. Id. at 80. He states that, after petitioner's Tdap in April 2008, petitioner "had many of the classic symptoms of anaphylaxis except his throat did not close." Id. Dr. Wilkinson states petitioner was allergic to dairy and the vaccine had casein in it. Id. He notes petitioner continued to have symptoms and had ongoing pain over the kidneys. Id. Petitioner had night sweats or felt very cold, plus he had headaches. Id. Dr. Wilkinson concludes, "This is what appears to me to be a drug reaction." Id. He then asks for input from the recipient of the letter. Id.

On November 24, 2009, petitioner saw Dr. Andrew G. Ayars, an allergist, and Dr. Reynold M. Karr, Jr., an allergist, at the University of Washington Medical Center. Id. at 30. Dr. Wilkinson asked them to see petitioner regarding a possible adverse reaction to Tdap. Id. Petitioner stated that he received Tdap in April 2008 and had an episode that evening of lightheadedness, tingling in his hands and feet, and over the next 24 hours, a rash which was red and vesicular, with distinct patches on his trunk, scalp, and forehead. Id. He had associated fever, nausea, and headache. Id. The lightheadedness and tingling in his hands and feet lasted about two weeks. Id. The rash lasted two to three months and he noted a residual rash in his

scalp. Id. Since then, he had multiple issues, including throat pain. Id. He took what he called "acid pills' and the pain resolved. Id. Petitioner also had a history of chronic diarrhea which improved with not eating gluten, casein, or soy, but still had episodes of it. Id. Petitioner complained of fatigue, diffuse pain in his back, arms, and legs, and night sweats. Id. at 31. He had a past history of asthma. Id. The doctors' impression was possible adverse reaction to Tdap, chronic fatigue, chronic diarrhea, chronic backache, arm, and leg pain, and history of throat pain and weakness. Id. They did not feel that all the symptoms about which petitioner complained could be related to his Tdap. They stated, "It is possible that the patient had an antibody-mediated reaction to the vaccination initially, which could have caused his rash, lightheadedness and overall sense of anxiety at that time, consistent with a possible anaphylactoid type reaction. It is unlikely, however. We recommend that patient not receive [the sentence is not finished, presumably the doctors meant petitioner not received further Tdap]. Would recommend checking tetanus titers if he does require a tetanus booster in the future." Id. The doctors did not think petitioner had a rheumatological disorder since he had a normal sedimentation rate and normal c-reactive protein. Id. They attributed petitioner's diarrhea to intolerance versus possible allergy, and recommended he continue to avoid gluten, casein, and soy. Id. at 33.

On December 14, 2009, Dr. Bethel filled out a VAERS (Vaccine Adverse Event Reporting System) form, stating that petitioner had a reaction two hours after his April 11, 2008 Tdap vaccination, which Dr. Bethel described as an "immune complex reaction" with: enlarged lymph nodes; difficulty breathing; asthma-like condition; swelling face; generalized urticarial; swollen eyes; dizziness; pain; feeling unwell; pain in head and chest; ringing in ears; hair loss; fever; fatigue; diarrhea; pain in bone and muscle; nausea; and migraine. Id. at 55-56. The form notes an initial report received on April 14, 2009 from petitioner's wife. It describes a male patient, with an autoimmune reaction to milk, who received Adacel (Tdap). Id. at 56. Per the reporter, the patient who had a pre-existing autoimmune reaction to casein suffered severe permanent damage after receiving Tdap. Id. Petitioner's wife sent follow-up information on June 1, 2009. Id.

On October 29, 2010, petitioner saw Dr. Biju Kunhiraman, an endocrinologist, for evaluation of adrenal insufficiency for which Dr. Wilkinson started petitioner on hydrocortisone. Id. at 4. Petitioner had fatigue prior to starting hydrocortisone. Id. Petitioner said his complaints started after he received a tetanus booster shot. Id. Petitioner reported headache, excessive salt craving, flushing, rash, unusual tanning, food allergy, change in hearing, sleep difficulty, tearing, loud snoring, palpitations, lightheadedness, abdominal pain, diarrhea, and joint pain and stiffness. Id.

TESTIMONY

Jennifer Simmons, petitioner's wife, testified first. Tr. at 8. She and petitioner have been married since 1994 and have three children, all of whom have allergies, particularly to gluten and dairy. Id. at 9, 12-30. Petitioner also had allergies, and sensitivity to gluten and dairy. Id. at 10. When he went off gluten and dairy, his health improved. Id. at 25-26. After petitioner received the Tdap vaccine in April 2011, he called her from work in the afternoon and said something was

wrong and he did not feel well. Id. at 35. He came home early and was sweating and in pain. Id. His left arm (which received the vaccine) was swollen and red, and his armpit was spongy. Id. at 36. The next day, petitioner had 103 degree temperature. Id. His lymph nodes swelled and he had hives around his trunk. Id. at 36-37. His chest and throat felt tight. Id. at 37. Ms. Simmons did some research and discovered there was casamino, a casein derivative, in Tdap vaccine. Id. at 38. Petitioner had to use an inhaler and had fatigue and a headache. Id. at 41. On the Tuesday after the vaccination, petitioner had flank pain. Id. Petitioner had acid reflux and then throat pain. Id. at 45. Petitioner's skin darkened and his joints were stiff and muscles painful. Id. at 51. Petitioner also has diarrhea. Id. at 52. In November 2008, Dr. Wilkinson checked petitioner's hormones and his cortisol level, which was suppressed. Id. at 56-57. Dr. Wilkinson prescribed hydrocortisone. Id. Petitioner's aldosterone level was also low, and Dr. Wilkinson prescribed that as well. Id. Petitioner improved. Id. Petitioner's testosterone was low and Dr. Wilkinson prescribed that, too. Id. at 58. Dr. Wilkinson took petitioner off acid blockers for his gastroesophageal reflux disease and put him on betaine hydrochloride, which eliminated the reflux. Id. Petitioner took out a $500,000.00 loan to buy into the partnership at his employer, which made him a partner in January 2009, but the firm later bought him out. Id. at 65-66.

Petitioner testified next. Id. at 97. He stated that his health was difficult when he was a child. Id. at 98. He had asthma, some hip arthritis, chest pains, headaches, and fatigue. Id. at 98-99. He went from being a chemistry high school teacher, to working in real estate, to selling insurance at his last employer. Id. at 99-100. In 2006, when he went on a gluten-free diet, his chest pain and hip arthritis improved. Id. at 102. When he went on a dairy-free diet, the bumps on his arms and his headaches went away. Id. at 104. Any time he drank milk, he would get a knot in his stomach. Id. at 105. In 2007, he had energy. Id. His average work day in 2007 was 10-11 hours if he was traveling. Id. at 108. After he received the Tdap vaccine in April 2008, his arm became very sore and red around the injection site. Id. at 111. He had some tingling in his arm. Id. He went back to his office and did not feel right, as if he were coming down with a cold or the flu. Id. He felt chills, called his wife, and went home early. Id. His heart was racing and he started sweating. Id. His armpit lymph node started swelling and became tender. Id. at 112. By the next day, the swelling was the size of a grapefruit. Id. He also had a headache. Id. He started getting asthma attacks. Id. at 113. He noticed the flank pain a two or three days after the vaccination. Id. at 114. Both his kidneys hurt. Id. at 115. He also had hives and fever. Id. at 120. He still has migraine headaches. Id. at 121. Dr. Wilkinson diagnosed petitioner with adrenal deficiency. Id. at 142. Petitioner is on full hormone replacement therapy for Addison's. Id. at 142-43. The diarrhea and the hives made it difficult for him to travel. Id. at 150. In addition to the hormone replacement to treat his adrenal insufficiency, petitioner is supposed to have a low-stress lifestyle. Id. at 151. He stated that working as an insurance agent was not low stress. Id. He would be in the bathroom at work because of the diarrhea and miss meetings and he would have to leave clients early. Id. His partners, although patient, told him in October 2009 that they were going to divest and they voted him out. Id. at 151-52. Petitioner left his employer on December 31, 2009 and has not worked since. Id. at 152, 137.

Petitioner's expert, Dr. Joseph A. Bellanti, an immunologist, testified next.[3] Id. at 200. His opinion is that petitioner has an immunologically-mediated disease, which a genetic susceptibility to allergies triggered and the Tdap vaccination exacerbated on April 11, 2008. Id. at 203. Because the Tdap vaccine contained casein (to which petitioner is allergic), it set off a series of immune-mediated tissue-injuring reactions affecting mainly three organ systems: the neurologic system, the endocrine system, and the immunologic system. Id. Each of those three major systems interacts and is interdependent and interrelated. Id. Starting in petitioner's childhood, he suffered from several asthmatic attacks, arthritic symptoms, and rashes. Id. When petitioner went off gluten and casein, he improved, but when he was exposed to them, he worsened. Id. at 204-05. The immune system consists of the innate (nonspecific immunity) and the adaptive immunity (specific immunity). Id. at 208. Five classes of immunoglobulin—IgG, IgA, IgM, IgD, and IgE—can be responsible for injury through abnormalities of the innate system as well as the adaptive system. Id. at 209. IgE triggers some allergies while IgG triggers injury in the innate immune system. Id. at 211. Petitioner is not sensitive to IgE antibodies, while non-IgE mechanisms triggers his allergy and asthma. Id. Petitioner suffers from celiac disease-like symptoms because of sensitivity to casein (milk). Id. at 214. He has IgA sensitivity which can manifest as celiac disease.[4] Id.

Dr. Bellanti testified that petitioner's sensitivity to casein was demonstrated by the fact that when petitioner went off dairy his symptoms improved markedly, but when he thought he was drinking coconut milk, which was actually dairy, his symptoms returned. Id. at 215. After the Tdap vaccination, petitioner did not have full-blown anaphylaxis, but he did have many components. Id. at 218. He had hives with skin lesions. Id. Petitioner also had swollen lymph nodes, wheezing, and diarrhea, which are all manifestations of the allergic reaction. Id. at 219. Dr. Bellanti explained that when someone has a serious anaphylactic reaction, he can produce neoantigens that are modified, i.e., the vaccine sensitization had the effect of setting everything else petitioner experienced in motion. Id. at 220-21. Dr. Bellanti believe that the Tdap set in motion a disarray of petitioner's immune system, including some immune dysregulation which perpetuated his propensity to autoimmune disease. Id. at 221. The immune system is a system of balance. Id. at 222. When a foreign substance sets off pro-inflammatory cytokines, in an allergic and autoimmune individual, there are too little T regulatory cells to balance the inflammatory cytokines, resulting in too much inflammation. Id. at 222.

Dr. Bellanti said that petitioner's post-Tdap severe headache and stiff neck were

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[3] Dr. Bellanti is Director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University, among other posts. Ex. 19, at 1. He is board-certified in allergy and immunology. Id. at 4. He is past president of the American College of Allergy and Immunology. Id. at 6. He is on the editorial board of Annals of Allergy, Asthma & Immunology. Id. He authored or co-authored 234 articles. Id. at 12-26. He wrote or edited 59 books or articles, including the latest edition of his text Immunology IV. Clinical Applications in Health and Disease (2012). Id. at 38-41.

[4] Dr. Bellanti referred to Exhibit 35, Bovine milk intolerance in celiac disease is related to IgA reactivity to α- and β-caseins, by F. Cabrera-Chávez, et al., 25 Nutrition 715-16 (2009), for the proposition that cow's milk can induce celiac disease-like symptoms due to IgA reactivity in some patients. Id. at 715.

examples of his central nervous system being involved in his reaction. Id. at 223-24. Allergy to casein is an example of immunologic injury. Id. at 224. Petitioner's Addison's disease is an example of endocrine injury. Id. Dr. Bellanti said that the reason petitioner did not have this panoply of injured systems before the Tdap vaccine was the intensity of the immune activation was not severe enough pre-vaccination to involve the other organs. Id. He noted that injecting someone is different than exposing someone to a substance by inhalation or ingestion. Id. at 225. The internal system includes the spleen, lymph nodes, and thymus. Id. The external system, called the mucosal system, includes the linings of the gastrointestinal tract and the respiratory tract. Id. Both the internal and external systems make up the immune system, but exposure to an antigen from an injection may be more intense. Id. Petitioner's grapefruit-sized lymph node after vaccination and, later, swollen cervical lymph nodes on the left were symptomatic of his reaction. Id. Adjuvants in the vaccine would augment the intensity of the immune stimulation. Id. at 226.

Dr. Bellanti said that petitioner's sensitization plus exposure to casein-containing Tdap would result in an anamnestic response because his B cells and T cells would expand rapidly following re-exposure, contributing to the intensity. Id. at 229. Dr. Bellanti recalled that petitioner's mother stated in her affidavit that petitioner reacted to his exposure as a baby to DPT vaccinations with high fever and fussiness. Id. at 230. Petitioner was probably sensitized to the casein in those vaccines as well as his repeated exposures to casein in common foods and toothpastes that kept his sensitivity at a smoldering level. Id. When he received the Tdap vaccine, that intense stimulation produced a tremendous anamnestic response. Id.

In conclusion, Dr. Bellanti testified that the Tdap vaccine petitioner received on April 11, 2008 caused petitioner chronic immune-mediated problems affecting multiple organs, including the skin, respiratory tract, and several other organs. Id. at 231. Medical literature supports a causal relationship between non-IgE forms of food allergy and immune system aberrations, resulting in tissue injury such a petitioner's chronic disease manifestations. Id. Petitioner had a known sensitivity to casein, resulting in a cascade of immune-mediated symptoms following vaccination. Id. The temporal sequence is appropriate for causation, resulting in serious clinical symptoms which persist. Id. at 232. Petitioner has both sensitivity and non-IgE allergy to casein. Id. at 235. Addison's has been associated with celiac (an autoimmune disease) and petitioner's celiac-type sensitivity made him vulnerable to Addison's because of the Tdap component of casein. Id. at 277, 278.

Respondent's expert, Dr. Arnold I. Levinson, an immunologist, testified next.[5] Id. at 303. Dr. Levinson explained that Tdap contains casein. Id. He does not like to use the word "allergic" for the same reason Dr. Bellanti does not like using it: there are multiple

[5] Dr. Levinson is Emeritus Professor of Medicine and Neurology at the University of Pennsylvania. Ex. B, at 2. He is board-certified in Allergy and Clinical Immunology. Id. He has been on the Department of Health and Human Services Vaccine Injury Panel since 2009. Id. at 5. He authored or co-authored 111 research publications. Id. at 9-17. He authored or co-authored 42 editorials, chapters, and invited reviews. Id. at 18-20. He and three others have a patent for "Vaccines for suppressing IgE-mediated allergic disease and methods for using the same." U.S. Patent No. 10/518,701, 09/01/2005. Id. at 21.

hypersensitivity immune-mediated mechanisms that can result in an adverse reaction to an antigen. Id. at 312. There are both IgE and non-IgE mechanisms that give rise to reactions. Id. at 314. Dr. Levinson's opinion is that petitioner had a reaction to the Tdap vaccine, but that his reaction did not last more than six months. Id. at 320. However, he also testified that he does not know how long petitioner's reaction lasted. Id. at 322. Dr. Levinson said that after petitioner's initial reaction, petitioner had symptoms of adrenal insufficiency, but he does not know the basis for petitioner's persisting symptoms. Id. at 320-21. Multiple immune mechanisms can mediate an autoimmune reaction as well as an "allergic" reaction. Id. at 323. Dr. Levinson stated petitioner had a hypersensitivity reaction to the Tdap vaccine. Id. at 328, 380. Dr. Levinson said petitioner's hypersensitivity reaction involved immune components of some type but he does not know what they are. Id. at 380. He said someone with sensitivity to casein could certainly manifest with gastrointestinal disturbances. Id. at 334. Based on petitioner's history of being ill when ingesting dairy, and recovering his health when he was off dairy foods pre-vaccination, Dr. Levinson agreed that petitioner has a sensitivity to casein. Id. at 399. A hypersensitivity reaction is an immune-mediated reaction. Id. at 342. The reason petitioner's left armpit swelled after his Tdap vaccination is that the vaccine activated lymphocytes and mononuclear cells traveling back and forth through the lymphatics and blood in this area. Id. at 343. To Dr. Levinson, this constitutes an over-enthusiastic response on the part of the immune system. Id. at 345. He said we do not know the exact molecular basis of that exuberant response. Id. at 346. He also said that we do not know the mechanism for an adverse reaction to tetanus vaccine. Id. Dr. Levinson opined that petitioner could have Addison's because he has some of the clinical symptoms of Addison's. Id. at 357-58.

DISCUSSION

To satisfy his burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.'" Althen v. Sec'y of HHS 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for receiving the Tdap vaccine, he would not have had an anaphylactoid-like episode, followed by continuing immune symptoms, culminating in Addison's disease, but also that Tdap was a substantial factor in causing petitioner's complaints. Shyface v. Sec'y of HHS 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioner was unable to give a specific biological mechanism explaining how his immune response to Tdap vaccine led to Addison's disease, which is autoimmune. But petitioners do not have the burden of proving a specific biological mechanism in order to prevail in their cases. As the Federal Circuit stated in Knudsen v. Secretary of Health and Human Services, 35 F.3d 543 (Fed. Cir. 1994):

> [T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344. . . .
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

The Federal Circuit stated in Althen, 418 F.3d at 1280, "While this case involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Close calls are to be resolved in favor of petitioners. Capizzano v. Sec'y of HHS, 440 F.3d 1317, at 1327 (Fed. Cir. 2006); Althen, 418 F.3d at 1280.

In addition, the Federal Circuit in Althen stated: "If the Vaccine Act does not require Althen to provide medical documentation of plausibility, then it cannot require her to demonstrate that her specific injury is recognized by said medical documentation of plausibility." 418, F.3d at 1281.

As the Federal Circuit stated in Knudsen, 35 F.3d at 549:

> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain [vaccinees] while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical

> institutes, pharmaceutical companies, and government agencies. The special masters are not 'diagnosing' vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [vaccinee's] injury. . . .

The undersigned found notable respondent's expert Dr. Levinson's testimony that he believes petitioner had an adverse reaction to Tdap, but he does not know the mechanism involved. Tr. at 320-21. Dr. Levinson termed petitioner's response to Tdap a hypersensitivity reaction. Id. at 328. Although he does not see how petitioner's Addison's disease is connected to that, his puzzlement fits exactly into the Federal Circuit's statement in Althen that we are dealing in a field bereft of complete and direct proof of how vaccines affect the human body. Both immunologic experts struggled to explain how petitioner's hypersensitivity reaction occurred, differing only in that Dr. Bellanti opined petitioner's Addison's was part of his reaction and Dr. Levinson denied it.

The undersigned is impressed by the continuity of allergic and immune symptoms petitioner had immediately following receipt of Tdap vaccine, proceeding over time into adrenal insufficiency, analogous to Addison's disease. Petitioner experienced an immediate allergic reaction to Tdap because he has an IgA sensitivity to casein, a milk product used in production of the tetanus toxoid portion of Tdap vaccine. This immediate allergic reaction led, over time, to more symptoms indicative of an adverse immune process, including hair loss, repetitive rashes, weakness, diarrhea, and ultimately to failure of his adrenal glands to produce cortisol and aldosterone, similar to Addison's disease, for which petitioner must take supplements. The fact that this Addison's-like disease is autoimmune is not an impediment to petitioner's entitlement to damages merely because his preceding symptoms were based on an IgA allergy, i.e., immune-mediated but not autoimmune. As the Federal Circuit has said repeatedly, the field of vaccine causation lacks complete and direct proof and must rely on circumstantial evidence. From the time he received Tdap vaccine, petitioner has been immunologically abnormal and his health severely damaged.

Petitioner always assumed he would get better. His doctors told him his illness would pass. Petitioner even borrowed $500,000.00 to buy into a partnership at his insurance company even though he had been symptomatic for eight and one-half months. He tried valiantly to fulfill the demands of his new job as a partner until his co-partners decided to buy him out and he was dismissed. There is no evidence of malingering here. His illnesses are real and, unfortunately, permanent. The undersigned accepts Dr. Bellanti's testimony in toto. Petitioner merits compensation.

Petitioner did not have full-blown anaphylaxis, which is why Dr. Bellanti and some of the medical records refer to his having had an anaphylactoid response to Tdap. Petitioner also does not have full-blown Addison's disease, which is why Dr. Wilkinson diagnosed him with adrenal insufficiency, prescribing hormones such as hydrocortisone and aldesterol that would also treat

Addison's. As far as the undersigned is concerned, these are distinctions without differences.

The issue in this case is whether an adverse reaction to a vaccination must adhere to strict categories such as allergy, immune-mediated, and/or auto-immune, or whether someone's adverse reaction can be composed of components of each category. Recognizing that in a non-Table case, which requires proving causation-in-fact, the actual diagnostic entity is not crucial to a ruling of entitlement, the undersigned holds that a blurring of the distinctions among the three categories of adverse reaction does not preclude a finding of entitlement to damages. As the Federal Circuit stated in Knudsen, the undersigned is not "diagnosing" petitioner's vaccine injury. 35 F.3d at 549. Suffice it to say, the undersigned accepts Dr. Levinson's description of petitioner's adverse reaction as a hypersensitivity reaction, and the undersigned credits Dr. Bellanti's opinion that this hypersensitivity reaction included petitioner's adrenal insufficiency.

After petitioner reacted adversely to Tdap vaccine, his reaction continued since his symptoms did not end. Moreover his symptomatology spread to include adrenal insufficiency and other hormonal problems. Respondent's expert Dr. Levinson agreed that petitioner reacted adversely to his Tdap, but he did not know how long petitioner's adverse response lasted. Dr. Levinson's hesitancy to put an endpoint to the reaction is due to petitioner's symptoms perduring and involving adrenal insufficiency, for which Dr. Levinson cannot pinpoint an exact mechanism.

The undersigned concludes it is reasonable to connect petitioner's entire immunologic reaction to his adverse response. We do not know the specific biological mechanism(s) causing petitioner's perduring reaction to the Tdap vaccine. However, the Federal Circuit in Knudsen states petitioners do not have the burden of proving a specific biological mechanism. Id. Respondent's expert Dr. Levinson agreed with Dr. Bellanti that there are multiple mechanisms that cause both allergic and autoimmune reactions. The undersigned accepts Dr. Bellanti's theory that the exposure of petitioner to casein in the Tdap vaccine was sufficient to create further sensitization, which continued his reaction to include adrenal insufficiency. The testimony of both immunologic experts reveals the paucity of knowledge in the medical field of describing what mechanism can explain immune-mediated/hypersensitivity reactions. No one questions the timing of petitioner's initial reaction in this case as indicative of causation.

The undersigned rules that petitioner is entitled to compensation.

CONCLUSION

Petitioner has prevailed on the issue of entitlement. The undersigned will schedule a telephonic status conference soon to discuss resolution of damages.

IT IS SO ORDERED.

Dated: November 5, 2015

/s/ Laura D. Millman
Laura D. Millman
Special Master